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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: WO 98/44870

(43) International Publication Date: 15 October 1998 (15.10.98)

(21) International Application Number: PCT/IB98/00530

(22) International Filing Date: 9 April 1998 (09.04.98)

(30) Priority Data:
970100134 10 April 1997 (10.04.97) GR

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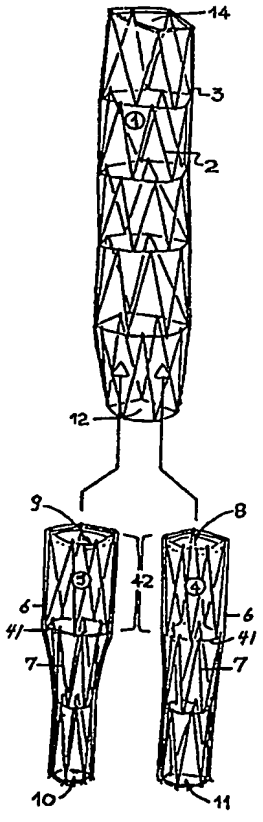
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: ENDOVASCULAR GRAFT FOR REPAIRING ABDOMINAL AORTIC ANEURYSMS

(57) Abstract

This is regarding a type of device aimed at a simpler, in relation to already existing techniques, endovascular positioning of a stent–graft in the abdominal aorta for the therapy of aneurysms up to the point of its bifurcation (26). This device is comprised of a system of three cylinders: a "main" (1) centrally placed and two "limbs" (4, 5) peripherally placed. Each of these cylinders has a central (14, 9, 8) and a peripheral (12, 10, 11) orifice. The cylinders are comprised of a cylindrical metallic skeleton which is self–expanding (2, 7) and made out of stainless steel or nitinol and which is externally covered with a cylinder (3, 8) made out of thin–layered PTFE, Dacron or some other elastic biocompatible material, refolded (18) around the peripheral orifice (12) of the skeleton of the main cylinder. These cylinders can be compressed into small diameter tubules (23, 27, 38) and enter the vascular lumen. After their insertion into the desired position, they expand, regaining their original diameter. The main cylinder (1) is placed inside the aorta becoming more circular when it comes in contact with the healthy part of the aorta (13) central to the aneurysm at the center of the orifice (14). The peripheral orifice of the main cylinder sits upon the expanded aortic bifurcation (26). The two limbs have a central orifice (8, 9) with a diameter equal to or approximately about 2 mm smaller than the diameter of the peripheral orifice (12) of the main cylinder. The branching of the main cylinder is accomplished by the entrance of the main ends of the two limbs inside the peripheral end of the main cylinder. Both limbs are at the same height in such a manner that they compress each other at the center of the cylinder. Each limb exerts equal pressure, whereas equal pressure is also exerted on the internal surface of the main cylinder from their external surface (FIG. 5) and together they both occupy at the height of their orifices the entire perimeter of the main cylinder (43). Alternatively, as limbs (peripheral cylinders), tubes of different diameters and types of skeletons can be used (28, 27).



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ENDOVASCULAR GRAFT FOR REPAIRING ABDOMINAL AORTIC ANEURYSMS

Description

The present invention relates to grafts for repairing aortic aneruysms.

The endovascular approach to aneurysms of the abdominal aorta is a new technique for the therapy of aneurysms by the placement of grafts which are transferred to the position of placement by means of the vascular lumen from easily anatomically approachable regions, thus avoiding the need for massive surgical operations. For the effective therapy of an aneurysm by this technique, it is necessary to have good circular application (contact) of the endovascular graft with the healthy, nondistended part of the blood vessel, so as to have complete exclusion of the distended arterial lumen by the pressure of the systemic arterial circulation, since the blood will now come out through the graft which substitutes for the vascular lumen. Furthermore, the endovascular graft must have a small starting-off diameter, which will allow its easy introduction and advancement from the entrance blood vessel to the position of placement, as well as its easy technical positioning. In abdominal aortic aneurysms there usually is a central neck region of the healthy blood vessel having a normal diameter underneath the kidney arteries (at the point where the graft is surgically attached even by the classical operation). However often the aortic distention is peripherally extended up the point of the aortic bifurcation at the two iliac arteries. This fact excludes the possibility of placing an endovascular tube graft due to the absence of a healthy peripheral contact point (neck). This often creates the necessity for the placement of endovascular grafts which can be attached to healthy regions of the iliac arteries more peripherally positioned to the distended aortic bifurcation with the simultaneous branching of the aortic blood flow to two cylinders of effluence. The systems that till now have been presented for the placement of aortic stent grafts composed, which are composed of, first off, of a stent graft or of grafts comprised of two parts are often complicated in their placement, have a large compressed size, and have imperfections in their support mechanisms and at their point of contact with the vascular wall. These

result in the appearance of immediate or future complications or in the inability of placement for a sufficient number of circumstances.

Furthermore, it is a device that, when combined with the fact that it has a limited number of parts, can serve a large number of circumstances of different anatomical dimensions.

According to the present invention, there is provided a graft arrangement for repairing an aortic aneurysm, the arrangement comprising a main graft, to be percutaneously introduced into the aorta via an iliac artery, the main graft being expandable and having a proximal orifice to be located in a part of the aorta adjacent to the renal arteries, the main graft also having a distal orifice end which when expanded serves to receive the proximal ends of a pair of expandable iliac artery grafts, wherein each graft comprises an expandable stent and at least one cover over and/or in the start, and wherein the cross-sectional area of the said distal orifice when expanded is sufficiently less than the sum of the cross-sectional areas of the proximal ends of the iliac artery grafts when expanded so as to form a seal with the said distal orifice when the pair of grafts are expanded therein.

The main graft can be selected to be of a length to extend from the said part to the bifurcation region wherein the aorta extends into the iliac arteries. Alternatively, the main graft can be of a length such that it extends only across the said part. The part of the main graft in the region of the distal orifice is reinforced in order to support the iliac artery grafts when expanded. It is preferred for these stents to be self expanding. The cover at the distal end of the main graft preferably extends beyond the distal orifice so that after the iliac grafts have been inserted and expanded, the extension to the cover enters the interior of the iliac grafts and forms an extra seal therewith. The start of the main graft can comprise hooks or barbs designed to enter the wall of the said part in order to assist in the attachment of that graft to the said part.

Brief Description of the Drawings

FIG. 1 is a schematic representation of the stent graft after its placement in the aneurysm of the abdominal aorta according to the present technique.

FIG. 2 is a schematic representation of the three parts of the central graft (main cylinder) and the two limbs (peripheral cylinders) from which are composed the stent graft according to the presented technique. The two limbs (peripheral cylinders) enter with their central region (of greater diameter) at the peripheral or distal region of the central cylinder and by their expansion create a leakproof branching of the central graft.

FIG. 3 is a representation of the analytical magnification of the central graft (main cylinder) which is placed in the abdominal aorta in the region between the out-branching of the kidney or renal arteries and the aortic bifurcation after its positioning and its expansion. At the peripheral end can be discerned the refolding and attachment of the thin-walled external covering inside the main cylinder, to reinforce it and to make the branching of the main cylinder more leakage proof after the placement of the two peripheral cylinders.

FIG. 4 is a magnified representation of the cylinders in their compressed form inside the storage tubules which are small in diameter equal to the diameter of the placement tubules inside the arteries as well as the propulsion device for the introduction and progression of the graft by means of a guide wire.

FIG. 5 is a three-dimensional schematic representation of the overlapping regions of the cylinder and of the two peripheral cylinders (limbs) after the expansion of the limbs inside the main cylinder and their leakage-proof application, not only amongst the limbs, but also with the central cylinder due to their self-expanding character. At cross-section, one can clearly see the variety of shapes that the central orifices of the limbs can take when restricted at their external surface by the internal surface of the central cylinders at their overlapping arts.

FIG. 6 is a schematic representation of an alternative manner of construction of the limbs of the stent graft where the diameter of the central orifice at one of the limbs at the length of >2 cm (covered by the central cylindrical part) is equal to the diameter of the peripheral orifice of the main cylinder while the diameter of the other limb is smaller at the center of the orifice and part as well as at the cross-section of the central orifices after the expansion of the two limbs inside the central tube. If they were allowed to expand naturally, the cross-sectional

areas of the combined limbs would be twice that of the distal, orifice or the central tube.

FIG. 7a is a schematic representation of the method of placement of the central graft (main cylinder). This is found compressed inside the placement tubule where it is advanced since the guide wire passes through the graft and is brought to the point of placement with the help of the propulsion device and by the guide wire. The central orifice of the placement tubule has already been advanced more central to the aneurysm and when the graft reaches the position of placement, it is allowed to expand by means of maintaining the propulsion device stable and by means of the peripheral attraction of the placement tubule toward the propulsion device in such a manner so that during its expansion the graft will maintain its position unchanged.

FIG. 7b is a schematic representation after the placement of the central graft a second guide wire is advanced from the other iliac artery and by the peripheral orifice of the main cylinder. On the guide wires of both sides the placement tubules are advanced by an X-ray shadowing ring at their central orifice, through the iliac arteries and through the peripheral orifice of the main cylinder inside the peripheral part of the main cylinder.

FIG. 7c is a schematic representation of the advancement of the two limbs inside the guide introduction tubules using the same technique as that for the placement of the central graft, and of their equal in height positioning by means of retraction of the introduction tubules when these are forwarded at an upright position which is at the same transverse level as the two limbs. The complete release of the limbs (peripheral cylinders) along with the simultaneous or the nonsimultaneous withdrawal of the introduction tubules of both sides results in the fact that the expanded parts of the limbs will come in complete contact with the peripheral nonexpanded healthy region of the corresponding iliac blood vessel at which the flow of blood is directed.

FIG. 8 illustrates an alternative arrangement in which the main graft is substantially contained within the region of the aorta containing the renal arteries. The distal end of the main graft is constructed in a manner similar to that in the other

embodiments. The two limbs extend from the iliac arteries into the distal end of the main graft and are sealed in a similar manner.

Detailed Description

In general, this device presents a stent graft for the therapy of abdominal aortic aneurysms without the need for the presence of healthy peripheral aortic walls (26), whereof the placement of one and only one graft tube would be possible. The need to avoid the pathological wall by airtightness in the nonexpanded part of the region of the iliacs is accommodated by the branching of the central graft (main cylinder) at two peripheral tubes so that the blood can be driven toward both iliac arteries (24, 25) from the central aortic graft. Furthermore, the described graft must have the ability to be compressed to a small starting-off diameter (FIG. 4), such that the advancement and placement in its compressed form is made possible by means of the small diameter tubes (37, 38) inside the vascular lumen from distant regions (from the femoral artery in the abdominal aorta) where released it can regain its original large diameter. This is accomplished in such a way so that it is able to achieve its leakproof perimetric contact with the internal surface of the healthy vascular lumen central and peripheral to an aneurysm. Till today, there have been proposed and used various devices for the accomplishment of the above goals. However these are often complicated and difficult in their usage with the subsequent appearance of complications during and after the operation. To use these devices it is necessary for those performing the operation to acquire lengthy experience and to have ample abilities. Aim of the device which will be described as well as its technical positioning is the simplification of the placement procedure, the minimization of the immediate and future complications and the enhancement of the percentage of successful clinical results with the goal of the possibility of a wide usage of the method of endovascular therapy of aneurysms for those patients where the placement of a stent-graft is necessary.

The herein presented stent-graft is a graft which is comprised of a central "main" cylinder or tube (1) that at the center of the orifice comes into contact with the external surface of the perimeter of the aorta at the level more central to the distended part of the aorta (13) while the periphery of the orifice sits upon the aortic

bifurcation (26). The diameter or cross-sectional area of the central or proximal orifice (14) of the main cylinder (1) is equal to or larger than the diameter of the healthy part of the aorta (13) on which the cylinder will be placed. The diameter or cross-sectional area of the peripheral or distal orifice (12) is constant and independent of whatever aortic diameter at the level of its bifurcation (28) where the cylinder will be placed. The length of the main cylinder (1) is determined by whichever length amongst the central point of contact in the aorta (13) and its bifurcation (26).

The main cylinder (1) comprises a stent on skeleton (cast) which is preferably cylindrical and/or metallic with a length that is substantially equal to the distance between the kidney or renal arteries and the aortic bifurcation. This skeleton has as starting-off predetermined diameter α and a compressed diameter β and consists of successive and connected amongst themselves cylindrical pieces of variable length and with a Z configuration made out of biocompatible metal with memory such as stainless steel wire or nitinol (a nickel titanium alloy with thermal memory). The connection of these parts of the skeleton can be accomplished either by sutures (16) which pass through the orifices of the last of the endcrests of each piece or by metallic joints (solderings) in such a manner so as to allow a certain amount of flexibility amongst the various Z parts of the skeleton whilst the length of the skeleton has as minimal as possible changes between its compressed and its starting-off diameter. The present plan of the skeleton is described extensively and consists of the skeleton (2) of the main cylinder (1) which is described in the figures as well as other plans of however, the self-expanding skeletons with similar properties and characteristics which will possibly save the basic idea of the creation of the bifurcation of the herein presented stent-graft. The stent can at its proximal end, have a plurality of barbs or hooks which can, upon expansion, rotate and penetrate part 13 for sealing and securement purposes.

The metallic skeleton or stent of the main cylinder on its outer surface is covered by a tube (3) to form a graft which has a central (14) orifice, and a peripheral or distal (12) orifice. The wall is preferably thin-walled and of PTFE, Dacron, polyurethane or another type of biocompatible plastic. Alternatively, the

inner and outer surfaces of the metallic skeleton (2) can be covered by cylindrical tubes (3), or it can be covered on its inner surface only by the cylindrical tube. This tube has a starting-off or proximal diameter which is equal to that of the metallic skeleton and it has a central and peripheral distal orifice and a main body. The central orifice (14) has a diameter which is preferably substantially equal to or greater than that of the healthy part of the aorta at the point of its contact (13) with the main cylinder more central to the aneurysm. The tube(s) of the graft is refolded or is not refolded at the central orifice (14) of the metallic skeleton (2) and is attached upon the central orifice of the skeleton by a series of connective sutures (44) at the end-crests of the central end of the (metallic) skeleton or stent. An outer covering can cover an outer enlargement at the outer proximal end of cylinder 1 to firmly engage part 13 and then a flap can extend inwardly into orifice 14 to improve the seal. The peripheral orifice of the graft has a diameter of 20 - 25 mm and is refolded (18) at a length of 0.5 -1.0 cm at the internal side of the peripheral or distal orifice (12) of the metallic skeleton where it is internally attached by single sutures at two or at three different points of the metallic skeleton (2). Thus the flow of blood after the placement of the main cylinder is accomplished inside the peripheral refolding of the graft of the main cylinder at the peripheral end and creates two or three pockets (petals) (41) minimizing the surface of the peripheral orifice (12) of the main cylinder. Additional attachment points can be used, if desired, to establish additional petals. The main cylinder (1) has a starting-off diameter, which is of the thin-walled covering cylinder (3) around the center (14) and periphery (12) of the orifice end around its body. The metallic skeleton (2) expands the cylinder to this diameter and to a compressed diameter much smaller than that of the original diameter in such a manner so that it can be compressed inside the storage tubule (23) which has a small diameter (FIG. 4) equal to that of the placement tubule (37) which is used for the advancement of the graft inside the blood vessels (FIG. 7a). During the compression of the main cylinder (1) inside the storage tubule (23) it has at its center a catheter (45) which is used for the insertion of the guide wire (21) (which after this it is removed) through the compressed inside the storage tubule main cylinder during the positioning process. The progression of the main cylinder to the placement position

is accomplished by its propulsion by the storage tubule (23) to the placement tubule (37), which as previously mentioned, has the same diameter. This is achieved with the help of a propulsion device (22) which moves upon the guide wire (21) which goes through the center of the main cylinder and in continuation through the aneurysm.

The herein presented stent-graft is also comprised of two peripheral cylinders (limbs) (4, 5) which preferably are self-expanding stents or skeletons (7) identical to that of the main cylinder (1) but of different dimensions (a series of Z casts). These are covered at their external surface by a thin-walled cylindrical tube (6), which have an identical or a different composition from that of the main cylinder (1), but are of different dimensions. The peripheral cylinders have central (8, 9) and (peripheral) distal (10, 11) orifices and a starting-off diameter and a compressed diameter such that it becomes possible for them to be placed inside a storage tubule (23) exactly in the same way as with the main cylinder but of a smaller diameter. They can be advanced to the corresponding placement tubules (37, 38) inside of the blood vessels. The thin-walled cylindrical tube (6) covers the entire length of the metallic skeleton (7) and is attached to the central (8, 9) and the peripheral (10, 11) end of the metallic skeleton of each peripheral cylinder. The skeleton (7) of the peripheral cylinders (4, 5) has a diameter in its expanded form equal to or greater than that of the thin-walled cylindrical tube (6) at each of its parts in such a manner so that it comes in complete contact at its external surface with the internal surface of the thin-walled cylindrical tube (6) which has a constant diameter at its expanded form and at each of its parts. The graft can be refolded to a small length <5mm and can also not be refolded inside the central orifice (8, 9) of the skeleton of each limb and is not refolded at the peripheral orifice (10, 11) of the skeleton of each limb where it is attached by sutures.

The diameter or diameters of the central orifice (8, 9) of each (peripheral cylinders) limb is preferably equal to or approximately up to about 5 mm or more smaller in relation to the diameter of the peripheral orifice (12) of the main cylinder. Alternatively, each orifice (8,9) can be equal to or greater than orifice 12, or each can be significantly smaller than orifice by much more than 5 mm such as 10 or 20

mm. Experimentation of a simple nature can determine sizes of the distal cylinders relative to orifice 12 in order to achieve a sealing affect between cylinders 1, 4 and 5. The diameter of the central orifice of each limb continues at a length of 2 - 2.5 cm at the central part (42) of the graft of each limb which is the length of the first of the Z casts of the preferably self-expanding stents or skeletons (7) of each limb and the point (41) where the first cast of the preferably metallic skeleton is connected to (jointed to) the second cast as has previously been mentioned. This central part (42) of each limb is the part which enters into the distal or peripheral end (43) of the central cylinder for the creation of the bifurcation of the central cylinder as will be mentioned in continuation. The diameter of the peripheral cylinders, more peripheral to the previously mentioned part, has a length and a diameter which vary according to the length and the diameter that is necessary so that the peripheral orifice (10, 11) of each of those two cylinders (4, 5) can come in complete contact with the healthy part of the corresponding iliac blood vessel (24, 25). That is to say, that the peripheral diameter and the length of each limb can differ from each other in relation to the dimensions of the iliac blood vessels of their healthy part and of the length of the damage of each, from the bifurcation of the aorta.

Alternatively, the diameter of the central orifice of the central part of each limb can differ in size (FIG. 8). Specifically, the diameter of the central orifice (30) and of the central part (46) of one of the limbs (28) which enters from the peripheral orifice (12) of the main cylinder (1) is equal to the diameter of the peripheral part and of the orifice (12) of the main cylinder, while the diameter of the central part (46) and the orifice (29) of the other limb (27) can be smaller with the aim of creating a smaller compressed limb diameter and its progression inside of a smaller in diameter placement tubule, percutaneously. In this case, the expanding ability of the metallic skeleton (31) of the smaller in diameter limb is equal to or greater than that of the metallic skeleton (32) of the limb with the greater central diameter. The length as well as the periphery of the peripheral orifice (33, 34) of each peripheral cylinder (limb) (27, 28) can vary as previously mentioned according to the dimensions of the iliac blood vessels and their condition.

As material for the thin-walled covering cylinder (8, 35, 36) of the metallic skeleton (7, 31, 32) of the peripheral cylinders (4, 5, 27, 28) one can use a cylinder made out of thin-walled polytetrafluoroethylene, Dacron, or another type of biocompatible plastic. This thin-walled cylinder preferably has the previously mentioned constant dimensions of the peripheral cylinders (5, 4, 27, 28) at its noncompressed form as well as after its expansion by the self-expanding metallic skeleton (2) internally. The material of the thin-walled covering cylinder (8, 35, 36) of the metallic skeleton of the peripheral cylinders can cover the cylindrical metallic skeleton at its external surface or at its external and internal surface or at its internal surface.

Technical Placement - Creation of a Bifurcation

The herein presented stent-graft is created by the placement of three cylinders (1,4,5) (main and two peripheral) of which it is composed and which is executed in the following manner:

After the percutaneous placement of the guide wire (21) from the femoral artery and in a head on direction towards the aorta, an angiogram is performed so as to determine the height of the kidney arteries (20). At this point, as well as at the point of the aortic bifurcation, the X-ray shadowed guided position is monitored by X-rays. On the guide wire is advanced with the help of a diastolic device, percutaneously, the introduction tubule (37) (sheath) inside of which the main cylinder will be advanced during its placement. The introduction tubule has at its central end an X-ray shadowed ring (40) and at its peripheral end it has a hemostatic valve. During its endovascular advancement, the introduction tubule (37) has inside of it a diastolic device which makes easier its percutaneous entrance into the artery. The introduction tubule is advanced inside the aorta so far in as necessary so that the X-ray shadowed ring at its central end will be found at a more central level than that of the out-branching of the kidney arteries (20). In continuation, the diastolic device is removed from inside of the introduction tubule (37). And on the guide wire (21) through the hemostatic valve, the storage tubule (23) is advanced which has a diameter equal to that of the introduction tubule which carries inside its lumen the compressed main cylinder (1) (of the stent graft) that has a length equal to that of

the distance amongst the point of the out-branching of the kidney arteries (20) and the aortic bifurcation (26) and a diameter of the central orifice (14) (after its expansion) which is equal to or greater than that of the aorta at the height of the central neck (13) directly underneath the kidney tubules.

The main cylinder (1) is advanced from the storage tubule (23) to the introduction tubule (37) and through this to the placement point with the help of a propulsion column (propulsion device) (22), which passes through the center of the compressed main cylinder. When the main cylinder (1) which casts an X-ray shadow in its entire length (metallic skeleton) is advanced inside the introduction tubule (37) between the guide points that have been placed at the out-branching of the kidney arteries (20) and the aortic bifurcation (28), the propulsion column (22) is maintained in a stable condition by its central end which restrains the peripheral end (12) of the main cylinder at the height of the aortic bifurcation. The introduction tubule (37) is attracted by the column (22) in a centrifugal direction in such a manner so that the main cylinder (1) is progressively released from the introduction tubule at its entire length and will expand (FIG. 7). When it comes into contact with the internal surface (13) of the aorta directly beneath the kidney arteries (20) it will become more rounder whilst the peripheral orifice sits upon the aortic bifurcation (26). In this way, the dislocation of the main cylinder becomes impossible due to the constant length of the metallic skeleton (2) of the main cylinder which is supported by the aortic bifurcation.

In continuation and after the de novo progression of the column inside the introduction tubule (37), it is advanced on the guide wire (21) through the peripheral orifice (12) inside of the main cylinder (12) so that the X-ray shadowing ring (40) will be found 2 - 2.5 cm more central to the peripheral orifice (12) of the main cylinder.

In the same way, one of the two peripheral cylinders (5) is advanced inside of the introduction tubule through the hemostatic valve. In this manner, its central end (orifice) (9) will reach the height of the X-ray shadowing ring (40) of the introduction tubule.

In continuation, percutaneous advancement of the guide wire (38) is achieved from the femoral artery of the other side after its percutaneous injection. The guide wire is centripetally directed with the help of a guide catheter through the

iliac artery (25) and through the peripheral orifice of the main cylinder which sits upon the main cylinder which sits upon the aortic bifurcation inside the lumen of the main cylinder. Advanced on the guide wire follows the second introduction tubule (38) with a diastolic device inside of it and an X-ray shadowing ring (40) at its central orifice. The second introduction tubule (38) is centripetally advanced through the peripheral orifice (12) of the main cylinder and up to the point where the X-ray shadowing ring at its central orifice is found at the same height (2 - 2.5 cm from the peripheral orifice inside the main cylinder) with the X-ray shadowing ring of the main orifice of the introduction tubule (37) of the femur of the other side (FIG. 7b) inside of which is already found the peripheral cylinder of the limb (5) of the other side at its compressed form. Inside the second introduction tubule end with the technique which was previously mentioned, the second peripheral cylinder (limb) (4) is advanced till the point where its central compressed end is at an equal height as that of the X-ray shadowing ring (40) of the introduction tubule (38) inside of which it is advanced as well as with the central end of the compressed peripheral cylinder (5) of the other side.

After they are X-ray monitored, the two compressed peripheral cylinders (limbs) inside of the introduction tubules have a position of equal height, both with their central end, 2-2.5 cm more central and inside of the peripheral orifice of the main cylinder; that is to say, at the point of the union (41) (joint) of the first with the second Z element of their metallic skeleton which has a corresponding length, the introduction tubules are withdrawn simultaneously or nonsimultaneous in a centrifugal or distal direction and the peripheral cylinders are expanded according to the technique which was mentioned previously for the main cylinder.

After the expansion, the two peripheral cylinders, these having a self-expanding skeleton, preferably each with an equal strength of expansion at the end covered by their main cylinder part extended, are compressed due to the greater total diameter of both in relation to the diameter of the peripheral part of the central cylinder by the main cylinder. In this way, they come into leak-proof contact with the internal surface of the wall of the central cylinder, but also between them but however, maintaining the diameter of both central orifices (8, 9) equal to the

diameter of the peripheral part (43) of the main cylinder (1). The shape of the central orifice of the two peripheral cylinders can vary, without these, however, coinciding completely due to the equivalent expansive ability of their metallic skeletons (FIG. 5).

Furthermore, the reversal of the external cover (19) of the main cylinder at the peripheral orifice (12) creates an additional valve mechanism at this level which hinders the escape of blood from the microchasms which may occur during the contact amongst the two peripheral cylinders, but also with the internal surface of the peripheral part (43) of the main cylinder.

In this manner, a blood leak-proof (without the escape of blood) bifurcation of the main cylinder (1) is created at two peripheral cylinders (5, 4) with an entrance orifice (9, 8) of variable shape and area.

The peripheral part of each peripheral cylinder (limb) has a length and a diameter of the peripheral orifice which is analogous to those of the corresponding iliac artery (24, 25), so that after its expansion, it will come in complete contact with the internal surface of the healthy part of the wall of the iliac artery.

After the placement of the "stent graft", according to the manner which was previously mentioned, the direction of the flow of blood is achieved inside of the "stent" graft from the height of the kidney arteries through the orifice of the two limbs and more peripheral to these inside of the iliac arteries with the simultaneous exclusion of the systemic arterial pressure and the blood circulation of the pathologically distended wall of the aneurysm of the aorta which also includes the aortic bifurcation.

In the FIG. 8 embodiment, the graft arrangement comprises a main graft 1 which is formed in a manner similar to graft 1 of the other embodiments. It comprises an inner stent and an outer covering 3, the latter extending upward to form a flap 3' which when the assembly is operational, folds into the graft limbs to assist the sealing process.

The main graft 1 is introduced into the part 13 of the aorta with the proximal end of the graft adjacent to the iliac arteries and with the distal end 40 of the graft adjacent to the distal end of the good tissue 13. The graft is expandable to form a force fit within part 13. If desired the graft 1 can be provided with hooks,

which upon expansion of graft 1, rotate and embed themselves into part 13 in a known manner. The graft 1 has an internal cross-sectional area at least at end 40, much less than the sum of the external cross-sectional areas of the limb members 6. The latter are introduced via their respective iliac arteries in a tube such as 37 and allowed to expand and for the seals with the main cylinder 1 and using the flap 3' of the cover extending beyond the provisional end of the cylinder 1. The latter is quite stable since it is supported by the firm or undiseased part 13 of the aorta and it's position is quite fixed. The round flap can have 2 slits at appropriate positions to facilitate entry into the two respective tubes.

In the above described embodiments, self expanding stents have been employed. If that is not desirable for any reason, then non self expanding stents can be employed, but that would necessitate the use of expansion means such as balloons could be used, such as those employed in angioplasty procedures.

Claims

1. A graft arrangement for repairing an aortic aneurysm, the arrangement comprising a main graft (1), to be endovascularly introduced into the aorta, the main graft being expandable and having a proximal orifice to be located in a part (13) of the aorta adjacent to the renal arteries, the main graft also having a distal orifice end which when expanded serves to receive the proximal ends of a pair of expandable iliac artery grafts, wherein each graft comprises an expandable stent and at least one cover over and/or in the stent, and wherein the cross-sectional area of the said distal orifice when expanded is sufficiently less than the sum of the cross-sectional areas of the proximal ends of the iliac artery grafts when expanded so as to form a seal with the said distal orifice when the pair of grafts are expanded therein.

2. A graft arrangement according to claim 1, wherein the main graft is selected to be of a length to extend from the said part (13) to the bifurcation region wherein the aorta extends into the iliac arteries.

3. A graft arrangement according to claim 1, wherein the main graft is of a length such that it extends only across the said part (13).

4. A graft arrangement according to claim 2, wherein the part of the main graft in the region of the distal orifice is reinforced in order to support iliac artery grafts when expanded.

5. A graft arrangement according to any one preceding claim, wherein each stent is self expanding.

6. A graft arrangement according to any one preceding claims, wherein the cover at the distal end of the main graft extends beyond the distal orifice so that after the iliac grafts have been inserted and expanded, the extension to the cover enters the interior of the iliac grafts and forms an extra seal therewith.

7. A graft arrangement according to any one preceding claim, wherein the stent of the main graft comprises hooks or barbs designed to enter the wall of the said part (13) in order to assist in the attachment of that graft to the said part.

8. This claim is regarding a type of stent endovascular aortic graft which consists of a central branched cylinder adjoined by two peripheral cylinders destined

for the endovascular therapy of aneurysms of the abdominal aorta by expansion at the level of the aorta's bifurcation. Furthermore, this claim is also about this device's technical construction, synthesis, arrangement and placement into the aorta without surgical intervention. The placement of the device is characterized by its progressive positioning into the lumen of the aorta. The device is brought to the desired position endoarterially from a distant blood vessel with the help of a guide-wire and a catheter both of which are positioned inside small in diameter tubules:

a. First off, a main self-sustaining cylinder with a predetermined length that is equal to the length amongst the kidney artery and the aortic bifurcation. It has a self-expanding central and a peripheral orifice with a diameter of compression and one of expansion consisting of a self-expanding metallic skeleton with memory externally covered with a thin-walled cylinder made out of PTFE, Dacron or another type of biocompatible plastic, that has a constant predetermined maximum diameter which defines the expanded diameter of the main cylinder at the center of the orifice at its body end at the periphery of the orifice.

b. And two self-expanding peripheral cylinders of variable length each having a central and a peripheral orifice with a compressed and an expanded diameter which are equidiameterical at their expanded diameter at their central part and with a diameter of the central part equal to or approximately 5 mm smaller than the diameter of the peripheral orifice and not necessarily equidiametrical to their peripheral parts. They are composed of self-expanding metallic skeletons with memory. Both have an equal strength of expansion a diameter equal to or greater than that of each peripheral cylinder at its respective part with the same shape and material and of a different shape, material and dimensions from that of the main cylinder. They are covered by a thin-walled cylinder made out of PTFE, Dacron, or another type of biocompatible plastic with a constant predetermined maximum diameter which defines the expanded diameter of the peripheral cylinders.

c. By the creation of a bifurcation of the main cylinder from the two peripheral cylinders whose placement is by way of guide wires and tubules which are introduced through the peripheral arteries of the bifurcation where the graft will be positioned and through the peripheral orifice of the main cylinder which sits upon,

and is supported by the aortic bifurcation at the same or at different times of transport and by the equal in height positioning of the compressed central parts of the peripheral cylinders internal to the peripheral orifice and the peripheral expanded part of the main cylinder. In continuation, there is the gradual or simultaneous restoration of the central and peripheral parts of the two peripheral cylinders back to their expanded diameter, where at the central orifice and central part of the peripheral cylinders, is greater than the total sum of the peripheral parts and that of the peripheral orifice of the main graft. The graft brings in hemostatic contact, the outer surface of the central part and the orifices of the two peripheral cylinders and with the inner surface of the peripheral part and also the peripheral orifice of the main cylinder. It maintains open their central orifices, due to the equal strength of expansion of their metallic skeleton and it guides the blood flow, branching it from the lumen of the main cylinder and into the lumen of the two peripheral cylinders without leakage.

9. The stent endovascular graft according to claim 8, is characterized by the fact that the thin-walled cylinder which externally covers the metallic skeleton of the main cylinder is refolded at its inner peripheral orifice by a length less than half of the diameter of the peripheral orifice of the main cylinder. It is attached to the internal surface of the metallic skeleton of the main cylinder at two or three places in such a manner such that the incoming blood flow at the refolding causes the falling forward of the parts of the refolded region of the thin-walled cylinder between the points of attachment and the inner peripheral orifice of the main cylinder and will minimize the area of the peripheral orifice at this level, stopping leakages due to imperfect contact of the internal surface of the main cylinder with the external surface of the two peripheral cylinders.

10. Stent endovascular graft according to claim 3, is characterized by a metallic skeleton of the main and of the peripheral cylinders, composed of successive ring-like parts of different lengths and diameters, consisting of a stainless steel wire with memory and each circular part having a shape of a different number of successive Z's. The rings are attached by a fiber to each other by means of openings

at the ends of each part or by some other type of joint or attachment amongst the ring-like parts.

11. Stent endovascular graft according to claim 8, which is characterized by a metallic skeleton of the main and of the peripheral cylinders which consist of stainless steel self-expanding with memory or of a nickel titanium alloy self-expanding with memory and whose shape serves claim 1(c).

12. Stent endovascular graft according to claim 5, which is characterized by a metallic skeleton of the main and peripheral cylinders that differ from each other in their shape, length, diameter and material with which they have been constructed.

13. Stent endovascular graft according to claim 8, which is characterized by peripheral cylinders having orifices of different dimensions and with the diameter of the central region inside the main cylinder being equal to that of the peripheral region to the peripheral orifice of the main cylinder. The diameter of the central orifice and the central region of the other peripheral region will be smaller, but will have a metallic skeleton with a greater expansion strength than that of the other cylinder, in such a manner so as to be able to maintain the orifice of the cylinder and thus serve claim 1(c).

14. Stent endovascular graft according to claim 8, characterized by a thin-walled cylindrical cover of the main and of the peripheral cylinders made out of PTFE, Dacron or another type of a biocompatible plastic for the cylinder that covers the external and the internal surface of the metallic skeleton.

15. Stent endovascular graft according to claim 8, which is characterized by a thin-walled cylindrical cover of the main and of the peripheral cylinders made out of PTFE, Dacron, or another type of biocompatible plastic which covers the internal surface of the metallic skeleton.

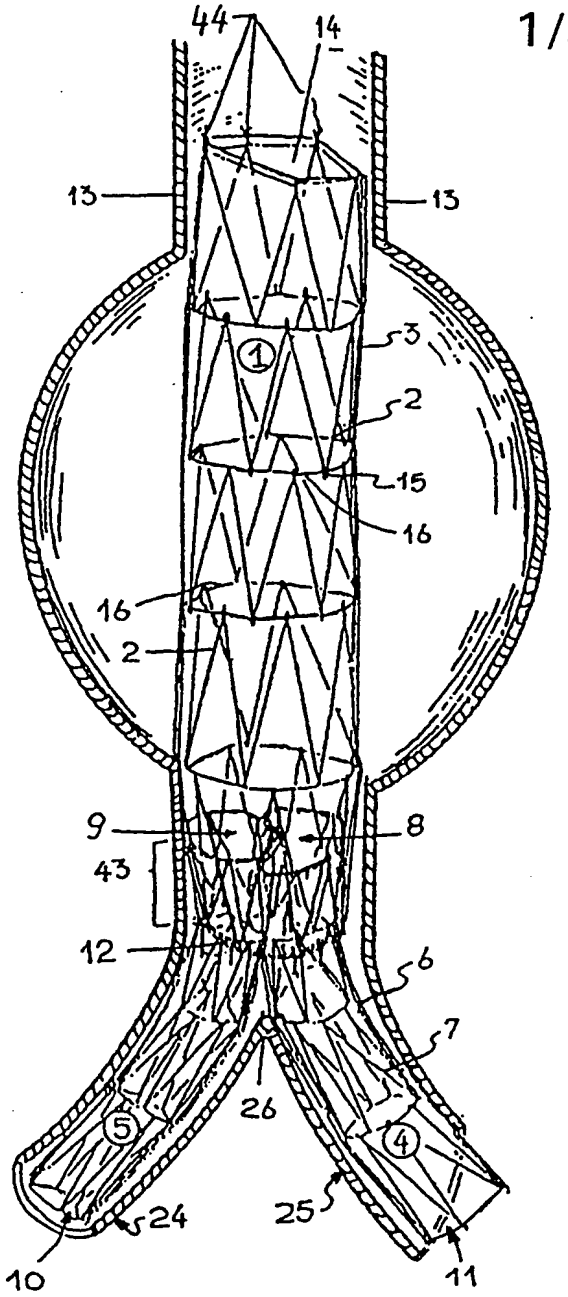
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FIG. 1

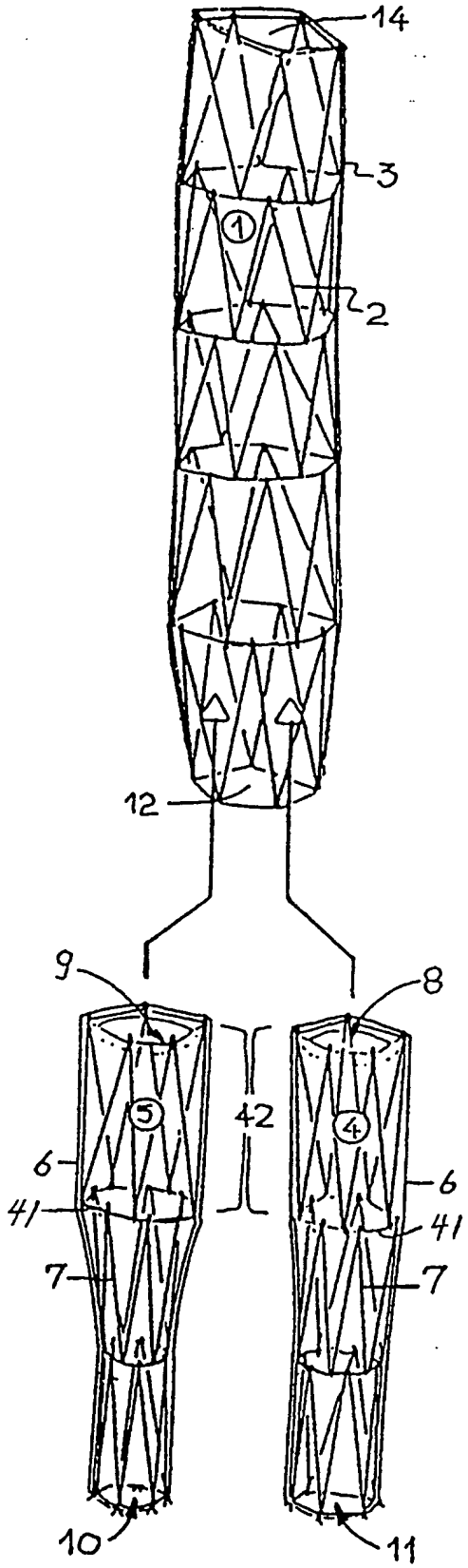
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FIG. 2

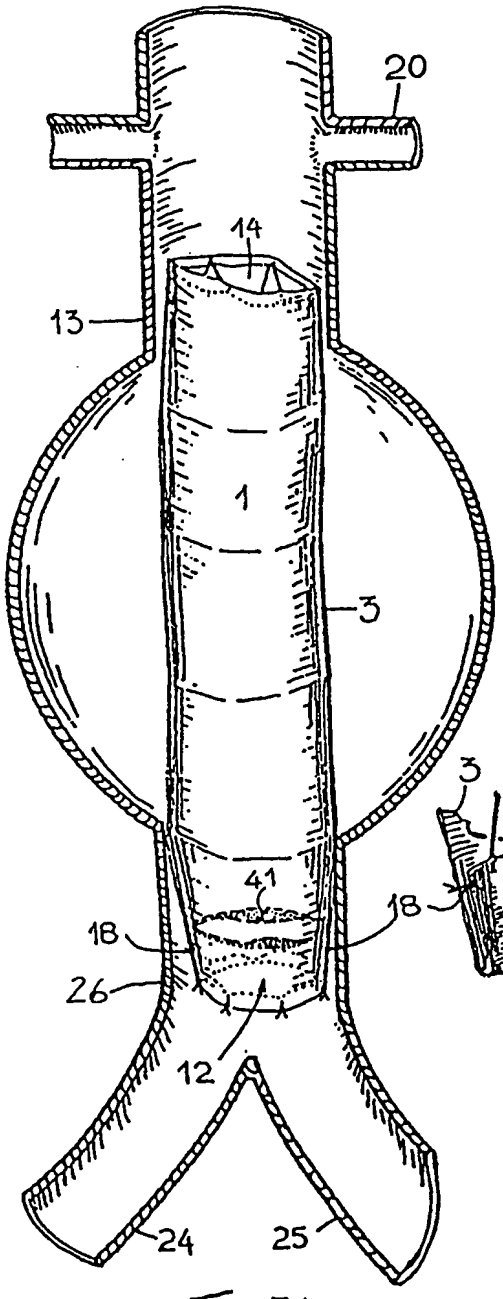


FIG. 3A

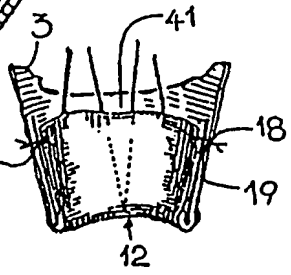


FIG. 3B

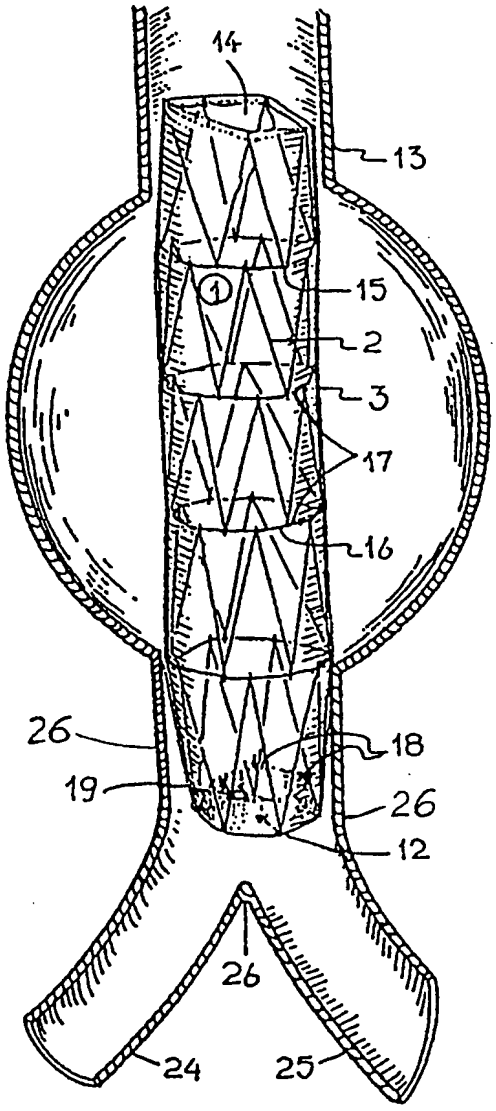


FIG. 3C

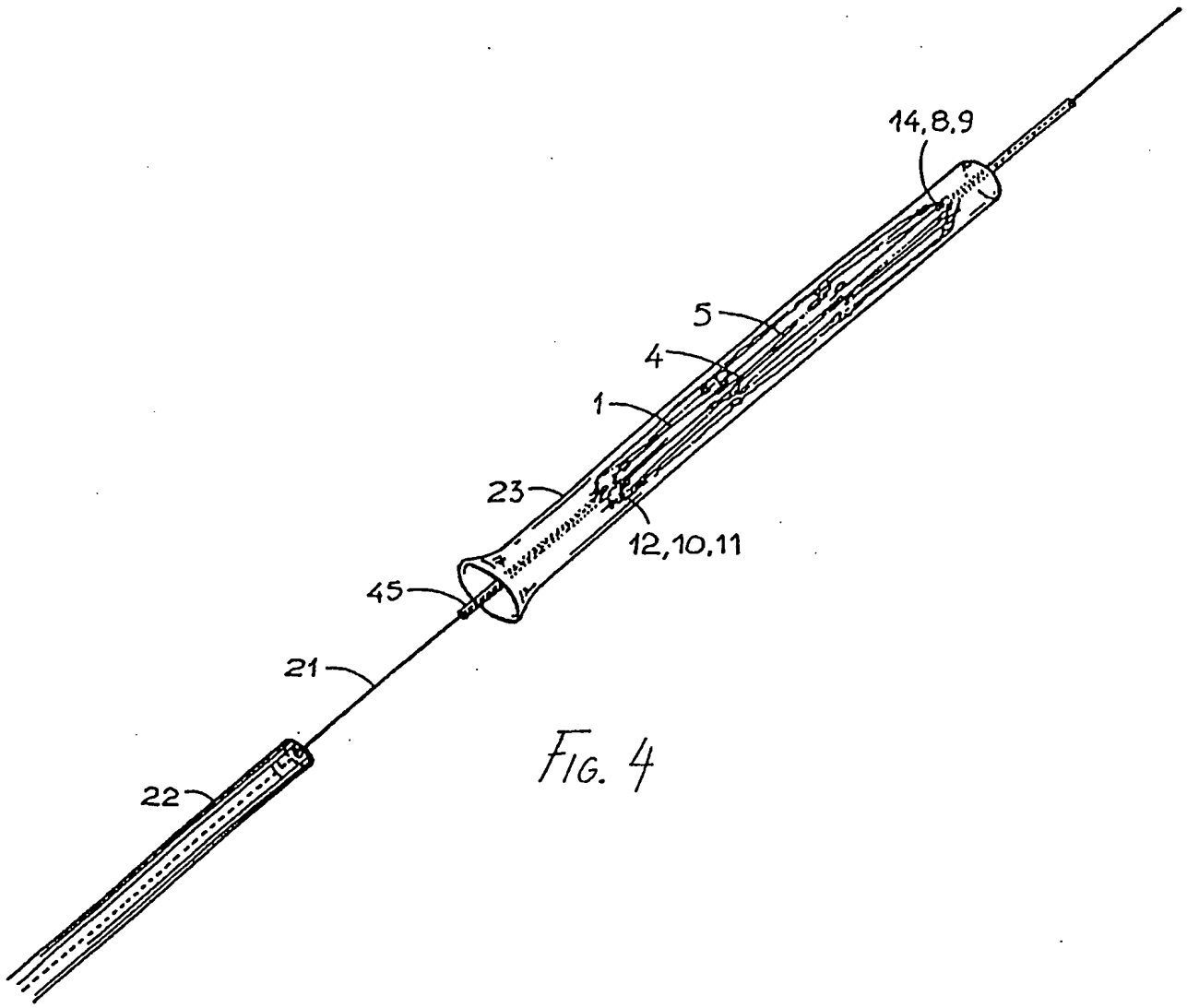


FIG. 4

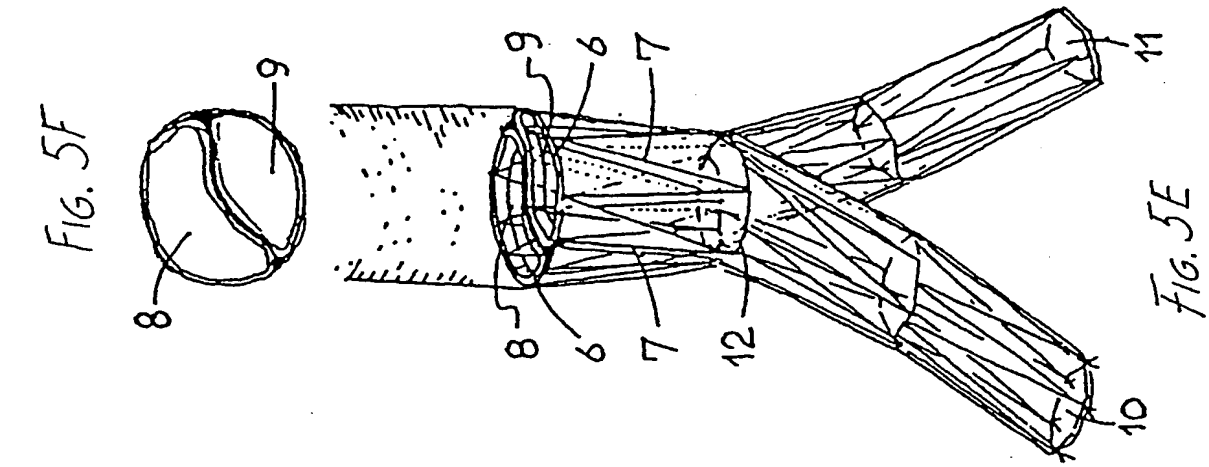


FIG. 5F FIG. 5E

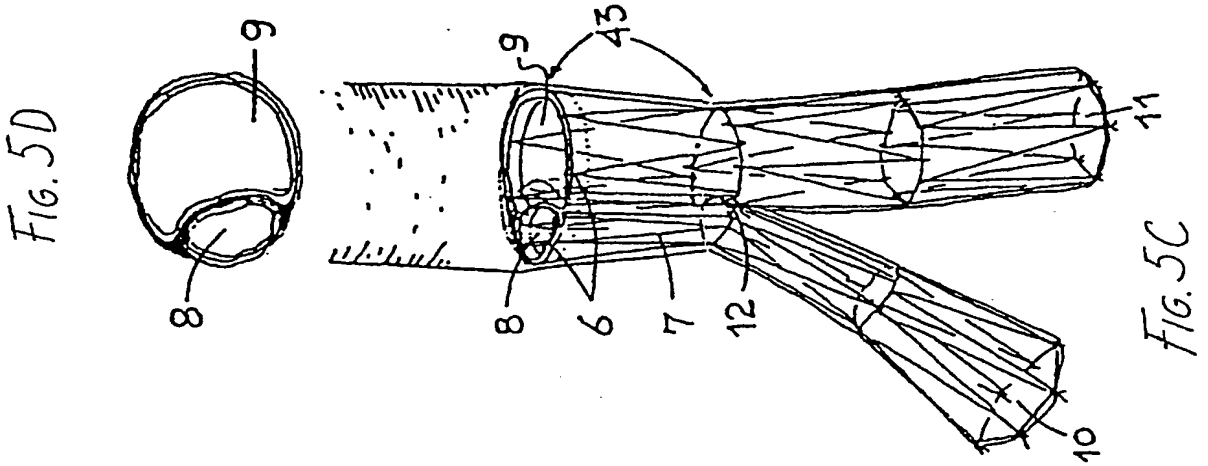


FIG. 5D FIG. 5C

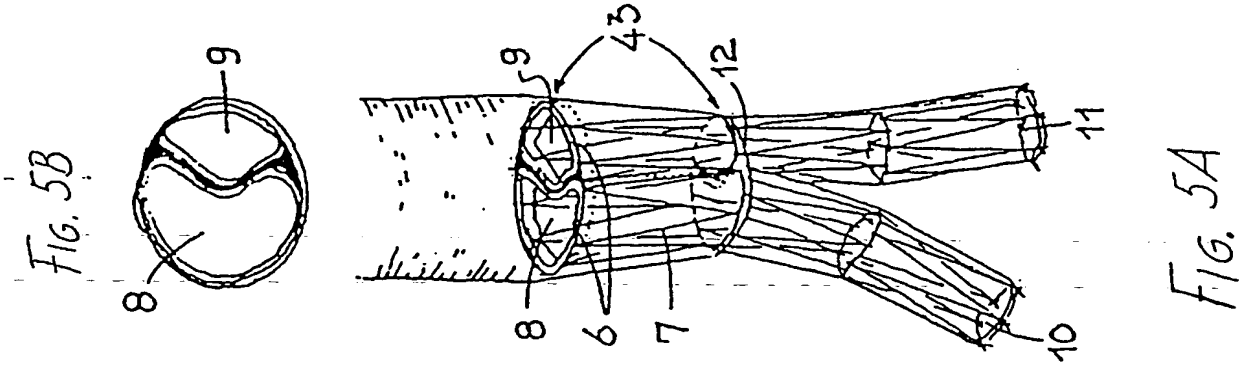
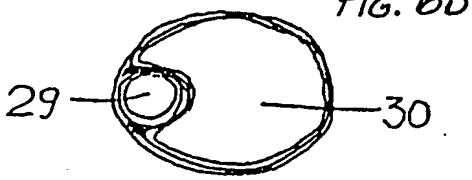


FIG. 5B FIG. 5A

FIG. 6B



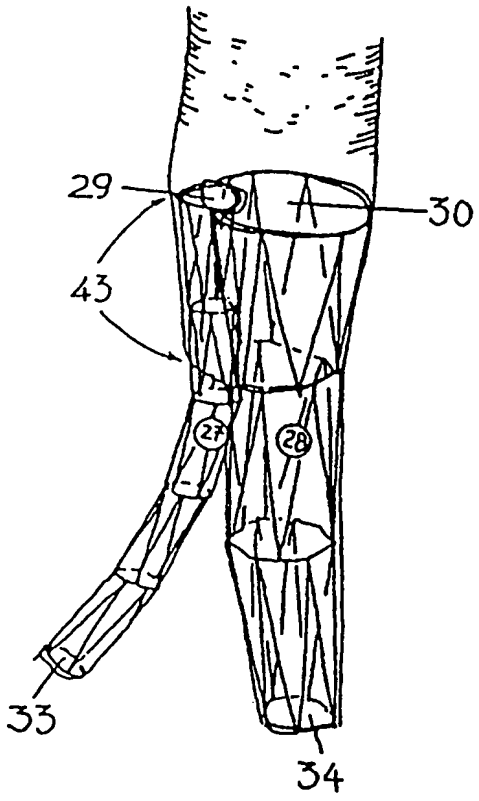


FIG. 6A

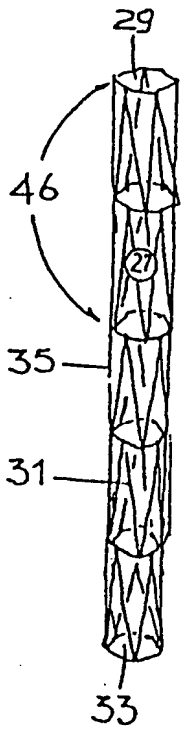


FIG. 6C

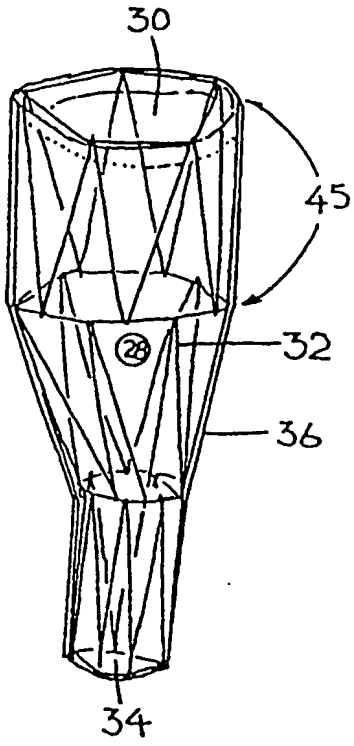


FIG. 6D

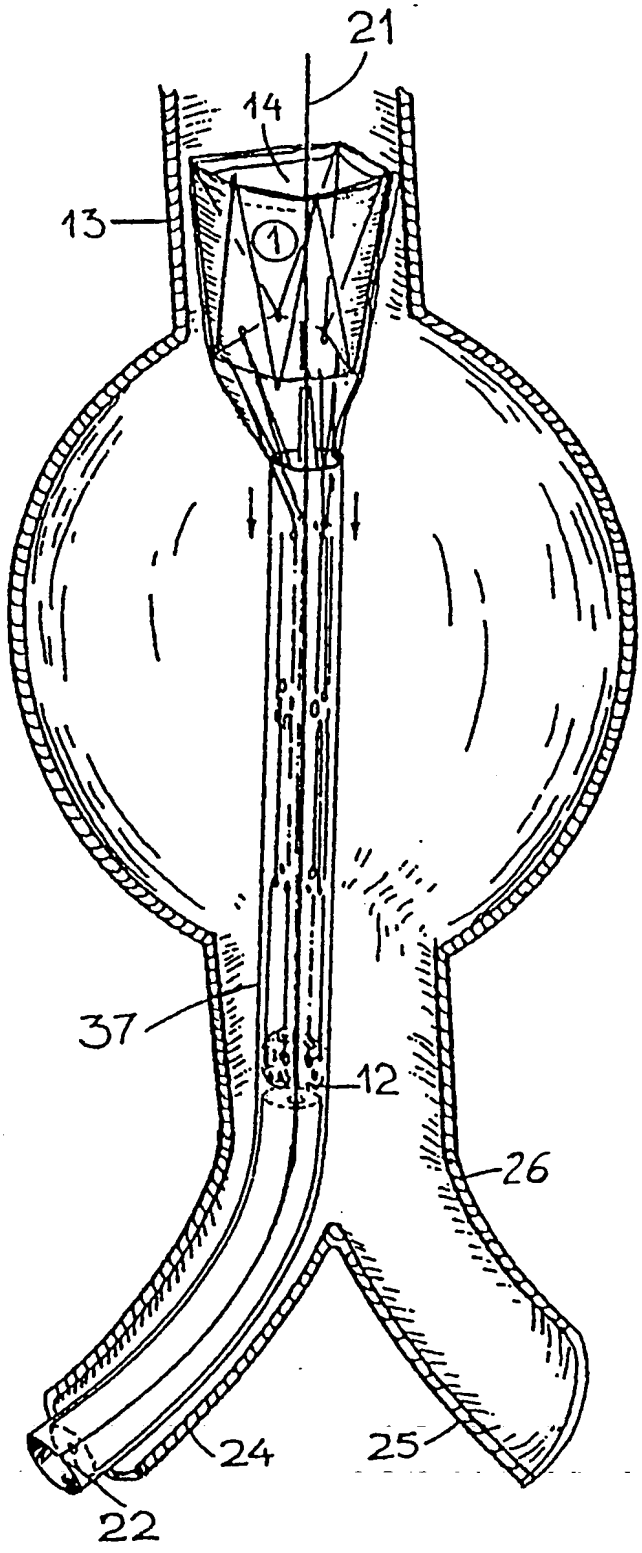


FIG. 7A

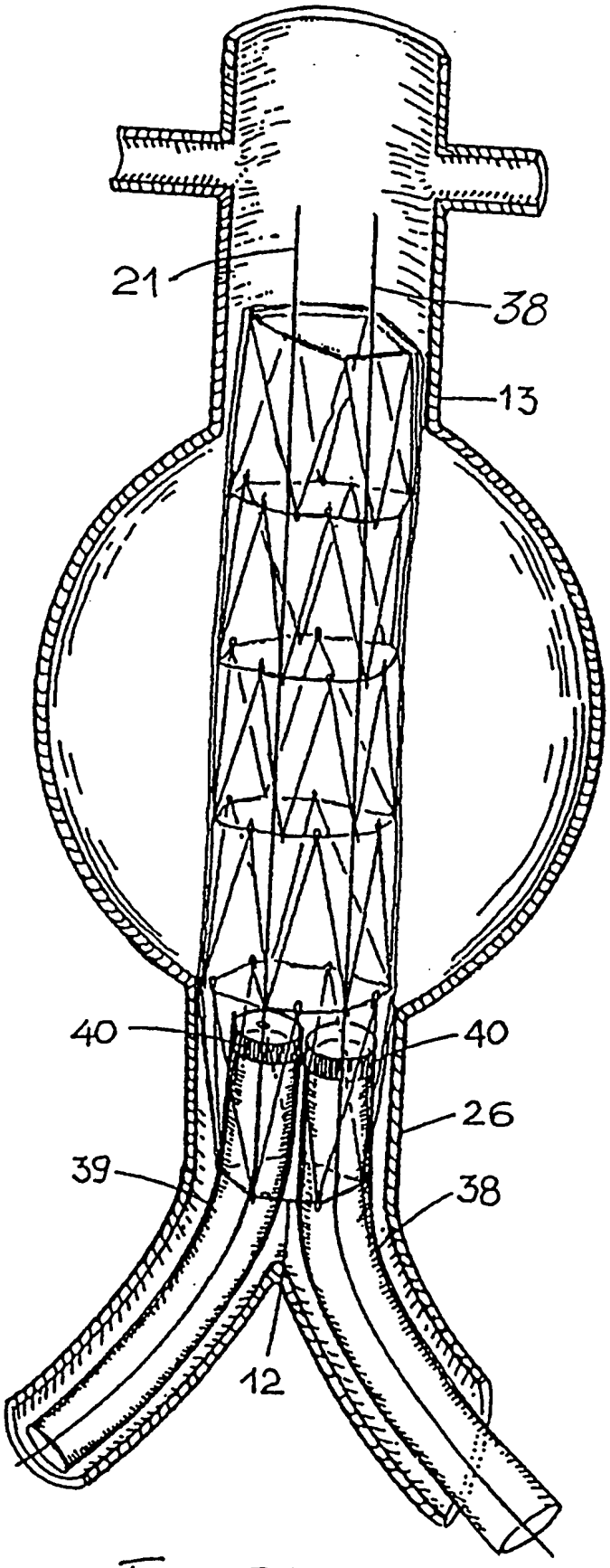


FIG. 7B

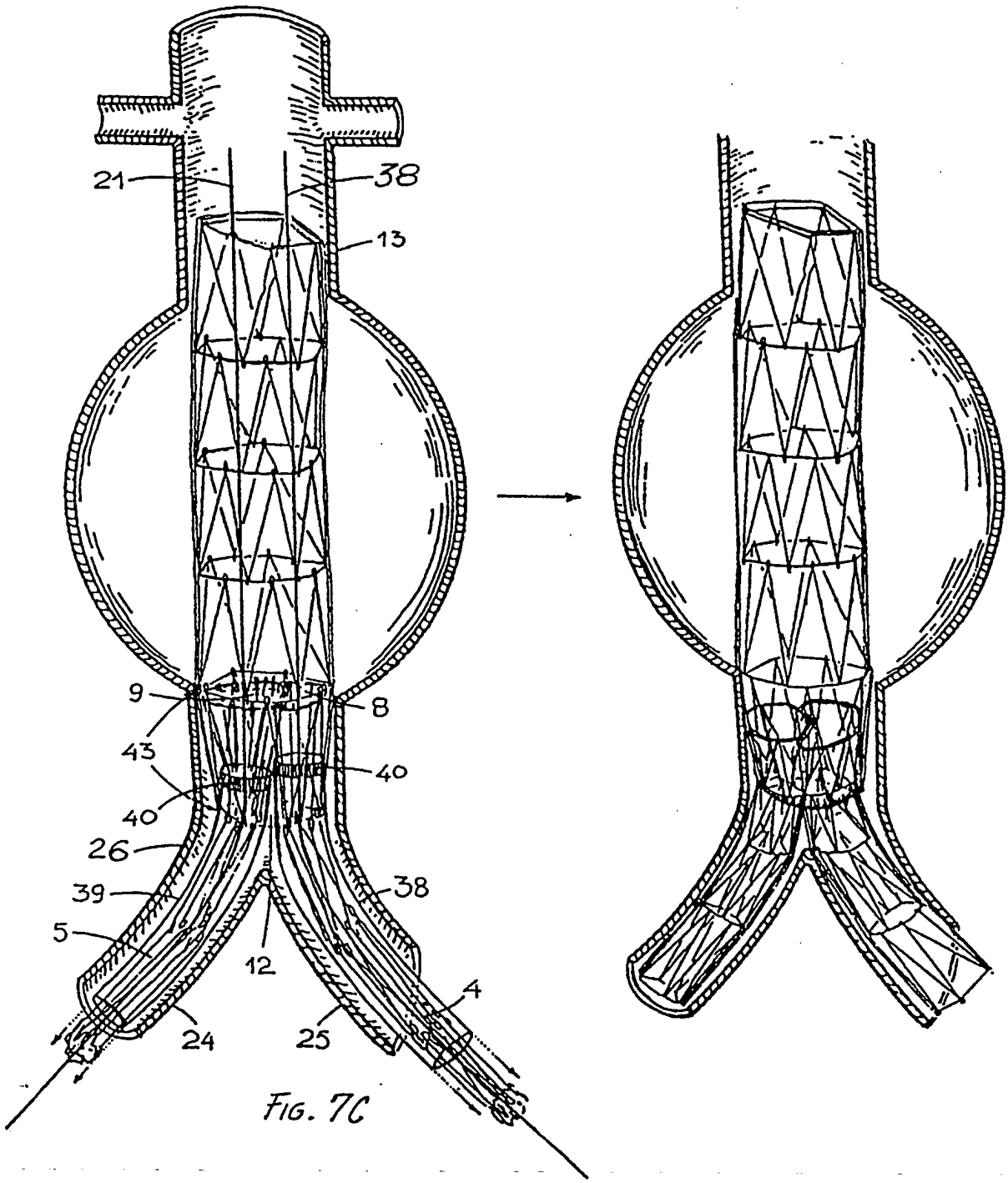


FIG. 7C

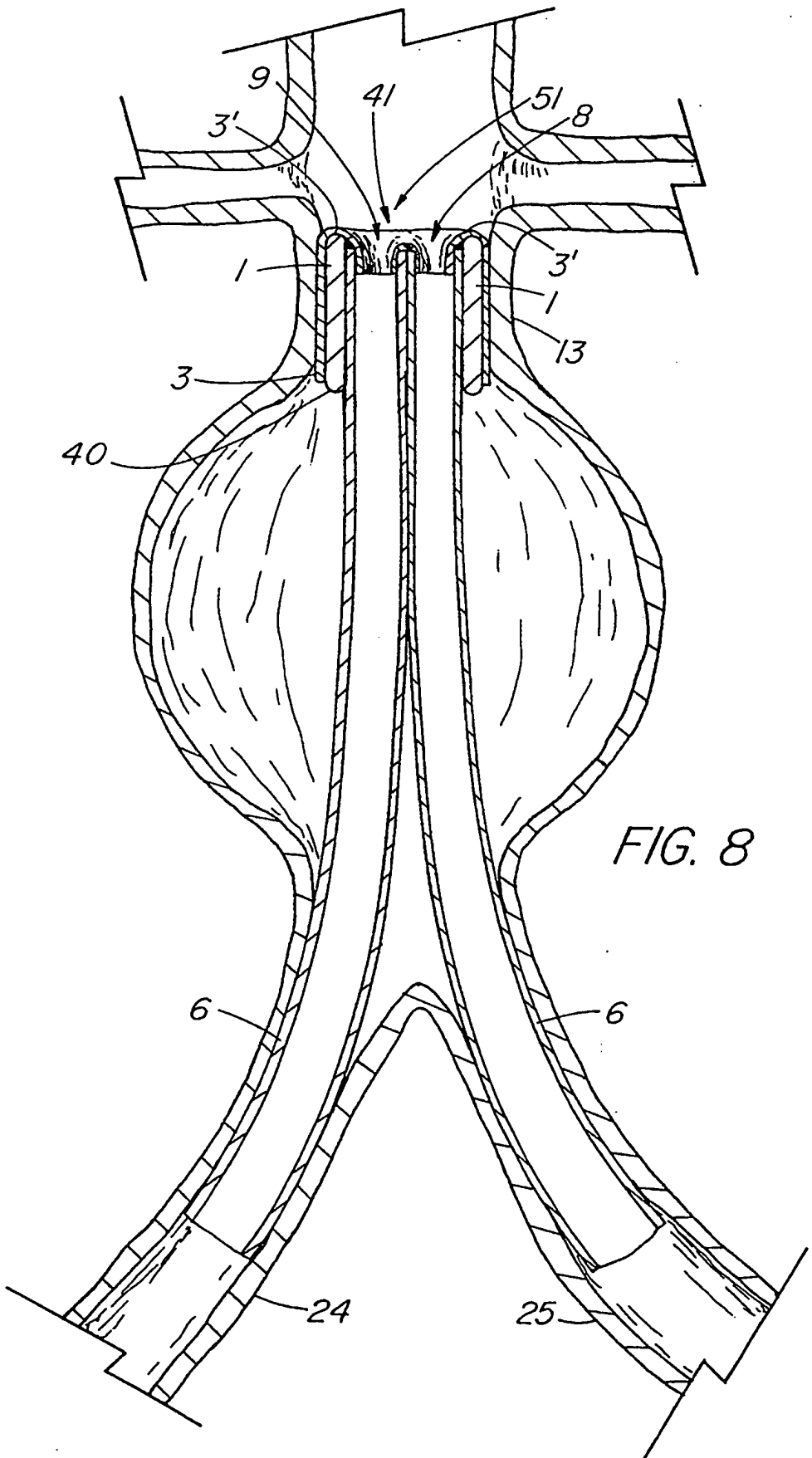


FIG. 8

INTERNATIONAL SEARCH REPORT

In: tional Application No
PCT/IB 98/00530

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WILSON G J ET AL: "A SELF-EXPANDING BIFURCATED ENDOVASCULAR GRAFT FOR ABDOMINAL AORTIC ANEURYSM REPAIR" ASAIO JOURNAL, vol. 42, no. 5, September 1996, pages M386-M393, XP000683606 ---	1,2,8
A	EP 0 686 379 A (CARDIOVASCULAR CONCEPTS, INC.) 13 December 1995 see column 12, line 43 - column 14, line 36; figures 5-12 ---	1,8
A	EP 0 765 643 A (DATASCOPE INVESTMENT CORP.) 2 April 1997 see the whole document ---	1,8
A	WO 95 21592 A (MINTEC, INC) 17 August 1995 ---	
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 July 1998	15/07/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/IB 98/00530

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 698 380 A (ETHICON, INC.) 28 February 1996	

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/IB 98/00530

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